

— National Patient Safety Partnership —

Statement Regarding Its Initiative to Reduce Preventable Adverse Drug Events

Various studies have shown that adverse drug experiences or events affect between 2 and 35 percent of hospitalized patients. Preventable adverse drug events represent a significant subset of these, if not a large majority of them. Little is known about the incidence of adverse drug events in outpatients, although they have been shown to be a significant cause of hospitalization and, consequently, increased health care costs. Indeed, adverse drug events are a cause of increased healthcare costs in all care settings.

For this initiative, a preventable adverse drug event (PDE)¹ is defined as an event that can be anticipated and forestalled and that will cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice, healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding or dispensing; distribution; administration; education; monitoring; and use.² Overall, PDEs are a serious public health and medical care problem because of the large number of drugs, doses, and drug treatment regimens currently available and the many changes in the manner that healthcare is provided today.

The National Patient Safety Partnership is a public-private partnership dedicated to improving healthcare in general and patient safety in particular by reducing adverse events and untoward outcomes of healthcare or healthcare-related processes. The members of the Partnership believe there are significant patient safety improvements that can be made through the prevention of avoidable adverse events associated with the prescribing, dispensing and administering of medications.

The members of the National Patient Safety Partnership believe that prevention of medication-related adverse events will be maximized when the outcomes of specific actions for improvement can be reliably predicted based on a strong body of evidence. It realizes that the current evidence base needs strengthening and believes that iterative improvement accompanied by outcomes analysis can advance the state of the science toward that goal. Based on current knowledge, the Partnership has identified a number of “best practices” or “model practices” that could substantially reduce the potential for occurrence of PDEs, and the Partnership calls on healthcare consumers, patient advocacy groups, the pharmaceutical industry, healthcare practitioners and healthcare organizations to make a commitment to adopt the practices listed below and to work together to implement them, as well as to develop additional ways to reduce PDEs.

¹ The differences between a PDE and the Food and Drug Administration’s (FDA) broader statutory definition of an adverse drug experience or event should be recognized. The National Patient Safety Partnership’s principal interest is advancing practices that prevent adverse events whereas the FDA’s principal interest is understanding drug/drug interactions and the biologic activity of drugs so they are fully labeled. At 21 CFR section 314.80 FDA defines an adverse drug experience as any adverse event associated with the use of a drug in humans, whether or not considered drug related, including the following: an adverse event occurring in the course of the use of a drug product in professional practice; an adverse event occurring from drug overdose, whether accidental or intentional; an adverse event occurring from drug abuse; an adverse event occurring from drug withdrawal; and any failure of expected pharmacological action.

² Adapted from the USP Quality Review – Definition of Medication Errors

Model Practices to Prevent Adverse Drug Events³

Current Best Practices For Patients/Consumers

The members of the National Patient Safety Partnership believe that all patients should be actively involved in their care and decisions concerning their care. There are many actions that patients can take, but the following two are stressed as ways to ensure that medication-related information is exchanged in a way that increases the probability of safe care.

1. Patients (or their personal advocates) should always inform their physician or other healthcare practitioner of all medications they are taking (NB: This includes prescription medication, over-the-counter medication and dietary supplements.) as well as about any and all allergies or previous adverse drug experiences they have experienced before accepting any new medication. Patients should not assume that information previously provided has been communicated or has been considered prior to a medication being prescribed or administered.
2. Patients (or their personal advocates) should request information about medications in terms that they can understand, both at the time the medication(s) is/are being prescribed and when they are received. This applies to prescription and over-the-counter medications. Patients should ask for information about the intended use or purpose of the drug, possible drug-drug interactions, potential hazards associated with taking several medicines (e.g., more than 3 drugs at the same time), and about changes in the appearance of any medications they have been taking (such as when a prescription refill is a different color from what had previously been taken). Before accepting or receiving a prescription, the patient should always ask the following questions:

Is this the drug my doctor (or other health care provider) ordered? What is the trade and generic name of the medication?

What is the drug for? What is it supposed to do?

How and when am I supposed to take it and for how long?

What are the likely side effects? What do I do if they occur?

Is this new medication safe to take with other over-the-counter or prescription medications, or dietary supplements, that I am already taking? What food, drink, activities, dietary supplements or other medication should be avoided while taking this medication?

In addition, at the time prescription medications are received from pharmacies, patients should ask if the drug they are receiving is the one their doctor or other health care provider ordered and ask that both the trade and generic names be listed on the prescription label.

³ The ordering of these "Best Practices" is not intended to suggest relative importance. The "Best Practices" are identified on the basis of eight techniques or criteria that have been shown to be important in reducing errors in general and medication errors in particular. The eight criteria are 1) ensuring timely access to information; 2) standardization; 3) simplification; 4) reduced reliance on memory; 5) reduced reliance on practitioner vigilance; 6) broad application; 7) cost effectiveness of the intervention; and 8) established success of the intervention. The 16 practices are used in the Institute for Healthcare Improvement Breakthrough Series.

Current Best Practices For Providing Organizations and Practitioners

The members of the National Patient Safety Partnership believe that healthcare organizations and practitioners are committed to safeguarding patients and call upon both organizations and individual practitioners to further advance the following practices and to support and advocate for these actions in areas and organizations in which they are not utilized.

3. Educate patients, family members and other caregivers about all medications (both prescription and over-the-counter, including dietary supplements) that are used. (Emphasis should be placed on the hazards of polypharmacy, drug-drug interactions and possible adverse effects.) Patients and caregivers should be encouraged to ask for information about all medications and dietary supplements, especially when new medications are prescribed or changes in medications are made.
4. Prominently display critical patient information, such as drug allergies and medication regimens, on every patient record.
5. Emphasize the need for dose adjustment in children and elderly patients. In some elderly patients, a reduction in dose may be required because of age-related changes in body mass and organ function.
6. Limit accessibility to and control the use of highly toxic or other high-hazard drugs such as potassium chloride or concentrated epinephrine.
7. Insist on the development and use of protocols for highly toxic or hazardous drugs with a narrow therapeutic range. (Computerized drug order entry systems can be especially important in facilitating this with alerts, restrictions or suggestions for safer substitutes.)
8. Computerize drug order entry whenever possible. If computerized drug order entry is not feasible, then use pre-printed order forms for drugs in inpatient settings and, where appropriate, in ambulatory care settings.
9. Utilize pharmacy-based intravenous (IV) admixture programs.
10. Avoid the use of abbreviations whenever possible; if abbreviations are used, they should be standardized throughout the organization and their use minimized.
11. Standardize approaches and processes for drug storage locations, internal packaging or labeling and delivery, and require use of the standardized approaches and processes.
12. Use unit dose drug distribution systems for inpatient care; also use such systems for outpatient care, where appropriate.

Current Best Practices For Purchasers

The members of the National Patient Safety Partnership believe that while most of these practices advocated in this initiative would cost little or nothing to implement, they do recognize that an investment will be required for some and call upon healthcare organizations and the pharmaceutical industry to make any needed investment in the interest of patient safety.

13. Require machine-readable labeling, such as a barcoding system, complete with pertinent information such as lot number and expiration date.
14. Preferentially purchase products that have labels with name of drug, concentration and warnings prominently displayed and that otherwise incorporate human factors evaluation into naming, labeling and packaging processes. (For example, the use of large type or contrasting colors to avoid look-alike packaging or unheeded warnings.)
15. Preferentially purchase and utilize “unit of use” packaging in inpatient settings; also use such packaging in outpatient (ambulatory care) settings, where appropriate.
16. Preferentially purchase intravenous (IV) solutions with contents and concentration prominently displayed on both sides of the container.

Even Better Practices in the Future

Finally, the members of the National Patient Safety Partnership believe it is imperative that the healthcare and pharmaceutical industries launch and sustain collaborations directed toward systematic approaches to the prevention of PDEs. The Partnership challenges these industries to seek opportunities for research and to seek collaborations to identify better practices in the future, to prioritize practice interventions, and to define practices that can predictably effect improvement in terms of increased safety and cost-effectiveness. Integral to such an activity is a non-punitive culture that encourages reporting of adverse or unexpected events to relevant oversight bodies, including internal quality management systems and regulatory agencies, and that provides feedback about resulting lessons learned and system changes aimed at preventing future such events. To be truly successful these activities must be ongoing since no solution that is found to any problem can be thought of as the “solution for all time”. A spirit of continual and relentless examination and reexamination will be necessary to insure that our processes and techniques are appropriate today and that they continue to evolve as necessary to be appropriate in the future as well.